

**Notice of Allowability**

Application No.

09/989,620

Applicant(s)

SERIZAWA ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response of November 21, 2003.
2. ☒ The allowed claim(s) is/are 1,4,13,14,18,27,28,44 and 46-51.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).**

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____  |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|  | 9 <input type="checkbox"/> Other  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Currently, claims 1, 4, 13, 14, 18, 27, 28, 44, 46-51 are pending in the application. Claims 1, 3, 4, 13, 14, 17, 18, 27, 28, and 44-48 were pending, and either rejected, or objected to as depending from a rejected claim, in the prior action, mailed on September 24, 2003. In the Response to this action, the Applicant cancelled claims 3, 17, and 45; amended claims 1, 4, 13, 14, 18, and 28; and added new claims 49-51. For the reasons indicated below, claims 1, 4, 13, 14, 18, 27, 28, 44, 46-51 are allowed.

### ***Claim Rejections - 35 USC § 103***

2. **(Prior Rejections-Withdrawn)** In the prior action, claims 1 and 3 were rejected under 35 U.S.C. 103(a) as being unpatentable over McGahon et al, British Journal of Haematology 101:539-47, in view of Ramer et al., U.S. Patent 6,001,962, and claims 1, 3, 13, 14, 17, 27, 28, 44, 45, 47, and 48 were rejected under 35 U.S.C. 103(a) as being unpatentable over McGahon and Ramer further in view of the teachings of Genestier et al. (J Clin Invest 102(2): 322-28) and Fujisawa et al., (J Clin Invest 98(2): 271-78). These claims read on compositions comprising a combination of the anti-Fas antibody CH11, and methotrexate. In view of the cancellation of these claims, or the deletion of the rejected subject matter from the claims, the rejections are withdrawn.

## **EXAMINER'S AMENDMENT**

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3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard S. Barth on January 12, 2004.

The application has been amended as follows:

In claim 4, the term "(FERM-58280)" was deleted, a comma was inserted after the phrase "a mouse-mouse hybridoma HFE7A," and the phrase - - deposited as FERM-5828- - was inserted between the inserted comma and the period.

In claim 18, the term "(FERM-5828)" was deleted from the last line of the claim, a comma was inserted after the phrase "a mouse-mouse hybridoma HFE7A," and the phrase - - deposited as FERM-5828- - was inserted between the inserted comma and the period.

In claim 49, the term "(FERM-5828)" was deleted from the last line of the claim, a comma was inserted after the phrase "a mouse-mouse hybridoma HFE7A," and the phrase - - deposited as FERM-5828- - was inserted between the inserted comma and the period.

In claim 50, the term "(FERM-5828)" was deleted from the last line of the claim, a comma was inserted after the phrase "a mouse-mouse hybridoma HFE7A," and the phrase - - deposited as FERM-5828- - was inserted between the inserted comma and the period.

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The amendments to the claims were made to correct the deposit number provided in claim 4, and to clarify the language of claims 4, 18, 49, and 50.

4. The following is an examiner's statement of reasons for allowance: Although the use of both methotrexate and the HFE7A antibodies for the treatment of the indicated disorders was previously known in the art, the Applicant has demonstrated an unexpected synergistic effect with the combination of the two compounds. Further, although the art does teach that methotrexate behaves synergistically in combination with certain anti-Fas antibodies, the art specifically indicated that anti-Fas IgM antibodies have this synergistic effect. McGahon, see 241, 542-46. Thus, because the art indicates that the HFE7A antibody is an IgG antibody (see, Serizawa et al., Saishin-Igaku 54(4): 917-24), and provides no reason for those in the art to believe that IgG antibodies would react synergistically with methotrexate, the claimed invention is found allowable over the prior art.

The deposit FERM-5828 was required by the Office Action mailed on March 26, 2003. The Applicant indicated that the deposit had been made with the National Institute of Biosciences and Human Technology on pages 18-19 of the application. However, the indication was not accompanied by the appropriate assertions as required by 37 CFR 1.801-1.809. (see, page 16 of the March 26, 2003 action). The required statements were submitted in the declaration filed by the Applicant on June 23, 2003.

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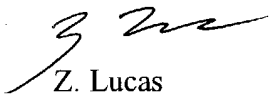
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

5. Claims 1, 4, 13, 14, 18, 27, 28, 44, and 46-51 are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner

  
JAMES HOUSEL 1/26/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600